Faculty Advisor CHECKLIST

New Review

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Reviewer: | | | Date: | | | | | | |
| PI: | | | Protocol ID: | | | | | | |
|  | | (Highlight One) Exempt Expedited Full | |  | |  | |  | |
|  | | **1. PRECHECK - MAIN PROTOCOL PAGE** | | **Yes** | | **No** | | **N/A** | |
| A | | Are all researchers listed on the informed consent also identified on the main Axiom protocol page as Principal Investigators (PI), Co-investigators, or student researchers?  Notes: | |  | |  | |  | |
| B | | Do all researchers (including students, faculty advisors, and external researchers) have copies of their human research subjects training certificates on file in Axiom under PI documentation? Are all certificates valid (80% or above) and non-expired?  Notes: | |  | |  | |  | |
| C | | Is the proposed start date at least 30 days from the date of receipt of the application?  Notes: | |  | |  | |  | |
| D | | Is the PI a Messiah student? Is the Faculty advisor (FA) a full time Messiah employee? Or if the FA is a Messiah adjunct, will the dates of the research fall within the dates of their current contract with Messiah?  Notes: | |  | |  | |  | |
|  | | **2. PROJECT DESCRIPTION** | |  | |  | |  | |
| A | | Does the protocol provide a clear rationale and sufficient background information to justify the research study?  Notes: | |  | |  | |  | |
| B | | Is the research question clear and able to be answered with the proposed research methodology?  Notes: | |  | |  | |  | |
| C | | Does the literature review provide ample background on the research question and  justification for the proposed research? Are the citations relevant and recent?  Notes: | |  | |  | |  | |
|  | | **3. PARTICIPANTS** | | **Yes** | | **No** | | **N/A** | |
| A | | Is the subject population described in sufficient detail?  Notes: | |  | |  | |  | |
| B | | Are inclusion and exclusion criteria clearly stated and reasonable? If certain populations are being excluded, is there a clear rationale for their exclusion?  Notes: | |  | |  | |  | |
| C | | Is the study limited to those over the age of 18? (If not, a full review may be required)  Notes: | |  | |  | |  | |
| D | | Are screening procedures described in adequate detail and acceptable?  Notes: | |  | |  | |  | |
| E | | If potentially vulnerable populations are included (e.g., children, pregnant women/fetuses, patients, students, employees, economically disadvantaged, mentally/cognitively impaired, at risk for losing services, LGBTQIA+), is there adequate justification and measures taken to reduce harm?  Notes: | |  | |  | |  | |
| F | | Are the participants students in the FA's class? If so, are all of the following provided:  - a letter from the chair or dean (if the researcher is also the chair) granting permission for the study  - a reasonable justification for the use of the researcher's own students (ease of access is not a sufficient reason)  - a clear and reasonable plan for reducing coercion and maintaining confidentiality of participants data  Notes: | |  | |  | |  | |
|  | | **4. RECRUITMENT** | | | | **Yes** | | **No** | | **N/A** | |
| A | | Are all recruitment documents provided (e.g., email, flier, etc.) and do the documents include  **ALL** of the following:  - statement that this is a research study  - description of the purpose of the study  - inclusion/exclusion criteria  - contact information for the researcher  - estimate of time commitment  - description of the procedures  - location of the study  - sponsoring institution  - statement that participation is voluntary  - identification of risks  Notes: | | | |  | |  | |  | |
| B | | If compensation is provided, is it mentioned in the recruitment documentation in a non-coercive  manner?  Notes: | | | |  | |  | |  | |
| C | | Are required permission to recruit documents provided (letters from instructors, department  chairs, external institutions, etc.)?  Notes: | | | |  | |  | |  | |
| D | | If social media is being used for recruitment, is a justification provided? Are social media posts  being made from a study specific social media account (no personal accounts)? Is permission to  post in social media groups documented?  Notes: | | | |  | |  | |  | |
|  | | | **5. STUDY PROCEDURES** | | **Yes** | | **No** | | **N/A** | |
| A | | | Do the checkmarks for chosen study design and type of data match the description of the project?  Notes: | |  | |  | |  | |
| B | | | Are all study instruments provided in a permanent file (no links to external sites)?  Notes: | |  | |  | |  | |
| C | | | If the location of the study is somewhere other than Messiah or an online survey, has permission been documented for that location?  Notes: | |  | |  | |  | |
| D | | | Is an adequate and reasonable timeline provided?  Notes: | |  | |  | |  | |
| E | | | Are the study procedures described in adequate detail? Is the described procedure reasonable and does it match the description on the recruitment and informed consent?  Notes: | |  | |  | |  | |
| F | | | Does the study involve any sensitive questions (relating to sexual orientation, illegal activity, breaking of Messiah institutional policies, abuse, violence, etc.), manipulation of psychological state, or exposure to potential bodily harm (this includes exercise, needle sticks, ingestion of substances, etc.)? If so, are adequate protections in place?  Notes: | |  | |  | |  | |
| G | | | Are all other study materials attached (e.g., questionnaires, interview questions, treatment protocol if applicable) and deemed acceptable after review?  Notes: | |  | |  | |  | |
|  | | **6. RISKS** | | | | **Yes** | | **No** | | **N/A** | |
| A | | Are all foreseeable risks described?  Notes: | | | |  | |  | |  | |
| B | | If over minimal risk (risks comparable to those ordinarily encountered in daily life or routine medical care), are risks minimized to the greatest extent possible? Are resources and contact information provided to report adverse events or seek assistance if necessary?  Notes: | | | |  | |  | |  | |
|  | | **7. BENEFITS** | | | | **Yes** | | **No** | | **N/A** | |
| A | | Are the benefits listed in the proposal reasonable and do they match the benefits listed in the recruitment and informed consent?  Notes: | | | |  | |  | |  | |
|  | | **8. Compensation** | | | | **Yes** | | **No** | | **N/A** | |
| A | | If compensation is being provided, is it adequately described and reasonable? If course credit or extra credit is being provided, is there an alternative assignment that provides the same credit for the same amount of time/effort?  Notes: | | | |  | |  | |  | |
|  | | **9. PROCEDURES TO MAINTAIN CONFIDENTIALITY** | | | | **Yes** | | **No** | | **N/A** | |
| A | | Are there adequate provisions to protect the privacy and assure confidentiality of subjects?  Notes: | | | |  | |  | |  | |
| B | | Has the plan for protecting confidentiality of data been adequately described including storage (location, duration) of data and access by others?  Notes: | | | |  | |  | |  | |
| C | | Does the proposed research follow all Messiah IRB policies including double-locks on data, use of Messiah owned devices/software/storage for collecting and storing data, and use of Messiah preferred data collection tools (Qualtrics, OneDrive)?  Notes: | | | |  | |  | |  | |
| D | | Have all direct and indirect identifiers to be collected been described and justified?  Notes: | | | |  | |  | |  | |
| E | | Are methods to protect identifiers or links to identifiers described, and are these methods adequate?  Notes: | | | |  | |  | |  | |
|  | | **10. POTENTIAL CONFLICT OF INTEREST** | | | | **Yes** | | **No** | | **N/A** | |
| A | | Are potential conflicts of interests disclosed and described?  Notes: | | | |  | |  | |  | |
|  | | **11. INFORMED CONSENT** | | | | **Yes** | | **No** | | **N/A** | |
| A | | Does the protocol describe the setting which consent is obtained (ensuring participant has adequate time, privacy, and free will to consider participation in an appropriate environment)?  Notes: | | | |  | |  | |  | |
| B | | Are all relevant elements of consent included in consent form (*all below need to be checked yes for approval; check N/A if consent does not apply due to waiver and skip to 12*) | | | |  | |  | |  | |
|  | | Information is in language understandable to participants and reps (age, education, and culturally appropriate) | | | |  | |  | |  | |
|  | | No exculpatory language through which participants/reps appear to waive legal rights | | | |  | |  | |  | |
|  | | Statement that the study involves research | | | |  | |  | |  | |
|  | | Explanation of purposes of research | | | |  | |  | |  | |
|  | | Expected duration of participation | | | |  | |  | |  | |
|  | | Description of procedures (including identification of any that are experimental) | | | |  | |  | |  | |
|  | | Description of foreseeable risks/discomforts | | | |  | |  | |  | |
|  | | Description of potential benefits (and compensation if included) | | | |  | |  | |  | |
|  | | Description of alternatives to participation including non-participation | | | |  | |  | |  | |
|  | | Description of how identifying information is privatized and maintained | | | |  | |  | |  | |
|  | | If more than minimal risk, information on resources to mitigate risks | | | |  | |  | |  | |
|  | | Who to contact in adverse event | | | |  | |  | |  | |
|  | | Contact information for the Provost’s Office | | | |  | |  | |  | |
|  | | Statement that participation is voluntary and participant can discontinue anytime | | | |  | |  | |  | |
|  | | Notes on informed consent: | | | |  | |  | |  | |
|  | | **12.OTHER CONSIDERATIONS** | | | | **Yes** | | **No** | | **N/A** | |
| A | | Are there appropriate resources to conduct research safely?  Notes: | | | |  | |  | |  | |
| B | | Is there appropriate monitoring of subjects during and after study (especially if study poses higher risk)?  Notes: | | | |  | |  | |  | |
| C | | Are translations of materials necessary, and if so, are translation procedures and resulting documents acceptable?  Notes: | | | |  | |  | |  | |
| D | | If deception is involved, is it justified and is an adequate debriefing protocol described?  Notes: | | | |  | |  | |  | |
| E | | If appropriate, are counseling referrals or support services provided?  Notes: | | | |  | |  | |  | |

**Recommendation:**

Highlight One: Approve Revisions Required (Explain Below)